



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,457	08/21/2003	Aurelian Bruneau	MSDI-266/PC771.00	7972

52196 7590 03/18/2008
KRIEG DEVAULT LLP
ONE INDIANA SQUARE, SUITE 2800
INDIANAPOLIS, IN 46204-2709

EXAMINER

PHILOGENE, PEDRO

ART UNIT	PAPER NUMBER
----------	--------------

3733

MAIL DATE	DELIVERY MODE
-----------	---------------

03/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/645,457

Applicant(s)

BRUNEAU ET AL.

Examiner

Pedro Philogene

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 68-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20, 68-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 10-15, 19-20 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Landry et al (2004/0147928) in view of Whitman et al. (6,517,565).

With respect to claims 1, 10, Landry et al disclose a device for guiding an implant to a location adjacent a bone anchor comprising: a guide member (100) including a connecting portion (104) and a guiding portion (102), wherein with the connecting portion adjacent the bone anchor said guiding portion extends proximally from the connecting portion and is adapted to receive the implant wherein the guiding portion is flexible, the connecting portion includes a body comprising a tapered portion forming a substantially uniform transition between the anchor and the guiding portion; as set forth in page 3, para [0051-0057], page 4, para [0063], para [0070], page 7, para [0100-0101], page 9, para [0112-0115] and as set forth in the claims ; and as best seen in FIGS.1-27.

It is noted that Laundry did not teach of a guiding portion positionable between an untaut configuration and a taut configuration; as claimed by applicant. However, in similar art, Whitman et al, column 5, lines 4-27, FIG.3, evidence the use of a shaft

Art Unit: 3733

portion that is flexible and positionable between an untaut configuration and a taut configuration such that the operator steers the flexible shaft portion as desired.

Therefore, given the teaching of Whitman et al, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Landry et al; as taught by Whitman et al to allow the operator to steer the flexible shaft portion as desired.

With respect to the above claims, it is noted that Landry et al discloses all the limitations, except for a connecting portion including a pair of extensions to releasably engage with the bone anchor; as claimed by applicant. However, in a similar art, Whitman et al, FIG.3, column 6, lines 38-67, evidence the use of an insertion instrument with a pair of extensions to releasably fasten and secure an implant.

Therefore, given the teaching of Whitman et al, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Landry et al, as taught by Whitman et al to releasably fasten and secure an anchor.

With respect to claims 2-6, 11-15, 19, 20, the above combination of references teaches all the limitations; as set forth in page 3, para [0051-0057], page 4, para [0063], para [0070], page 7, para [0100-0101], page 9, para [0112-0115] and as set forth in the claims; and as best seen in FIGS.1-27 of Laundry et al; and as set forth in column 5, lines 4-27, column 6, lines 38-67; and as best seen in FIG.3 of Whitman et al.

Art Unit: 3733

Claims 7-9, 16-18, 68-79 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Landry et al (2004/0147928) in view of Whitman et al. (6,517,565) in view of Beale et al. (6,440,133).

It is noted that the above combination of references teaches all the limitations, except for distal extensions each includes an engagement portion extending therefrom engageable with the bone anchor, the engagement portion each projects laterally from the respective distal extension, wherein the distal extension are deflectable toward one another for insertion into the bone anchor and biased toward a pre-insertion orientation to facilitate the engagement portion engaging the bone anchor; as claimed by applicant. However, in similar art, Beale et al evidence the use of distal extensions each includes an engagement portion (94e,f; 96ef) and as best seen in FIGS.6,9; extending therefrom engageable with the bone anchor, the engagement portion each projects laterally from the respective distal extension, wherein the distal extension are deflectable toward one another for insertion into the bone anchor and biased toward a pre-insertion orientation to facilitate the engagement portion engaging the bone anchor such that the extensions can be squeeze to hold the bone anchor and release to move apart from each other and release the bone anchor and with the engagement portions inserted into indentations in the bone anchor.

Therefore, given the teaching of Beale et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Landry/ Whitman et al, as taught by Beale et al., such that the extensions can be squeeze to hold the bone anchor and release to move apart from each other and

Art Unit: 3733

release the bone anchor and with the engagement portions inserted into indentations in the bone anchor.

Response to Amendment

Applicant's arguments filed 12/12/07 have been fully considered but they are not persuasive. In response to applicant's argument that "Whitman is non-analogous art that cannot be fairly used in the asserted obviousness rejection". is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, The question is not whether the combination was obvious to the applicant but whether the combination was obvious to a person of ordinary skill in the art. Given the problem to be solved, under the correct analysis, any need or problem known in the field and addressed by the patents can provide a reason for combining the elements in the manner claimed. it is common sense that familiar items may have obvious uses beyond their primary purposes, and a person of Ordinary skill often will be able to fit the teachings of multiple patents together like a piece of a puzzle .Regardless of Whitman primary purpose, it provide an obvious example of a shaft portion that is flexible and positionable between an untaut configuration and a taut configuration such that the operator steers the flexible shaft portion as desired, and the prior art was replete with patents indicating that such a shaft portion was ideal for a medical device. In addition, where there is a design need or market pressure to solve a problem, and there are

Art Unit: 3733

infinite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp.

The argument that those of skill in the art would not modify the guide member 100 to arrive at the invention of claims 1 and 10; i.e., to include a guiding portion positionable between an untaut and taut configuration, is not found to be persuasive. In para [0052], Landry et al disclose that "In some embodiments, stiffer sections of flexible member 100, such engagement section 102, may allow for small alignment variability proximate a threaded member. Therefore, Landry et al discloses that the guiding element could be stiff and at the same time flexible and also allow for some small alignment variability. Whitman et al disclose that guiding shaft could have a taut and untaut configuration to steer (allowing some small alignment variability) the flexible shaft as desired. Therefore, combining the references would have been obvious to one having ordinary skill in the art.

Conclusion

A shortened statutory period for reply to this action is set to expire THREE MONTHS from the mailing date of this action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (571) 272-4716. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272 - 4719. The fax phone

Art Unit: 3733

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Pedro Philogene/
Primary Examiner, Art Unit 3733
March 7, 2008